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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/770,603 | 01/26/2001 | Arthur E. Schwartz | 20076-53 | 8546 |

7590 02/21/2003

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EXAMINER

RAM, JOCELYN DEBRA

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/770,603 | SCHWARTZ, ARTHUR E. <i>MF</i> |
| | Examiner | Art Unit |
| | Jocelyn D Ram | 3739 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 December 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 20-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 20-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on 26 December 2002 is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-28, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Saab (5,624,392). Saab shows a catheter (10) for intravascular corporeal cooling comprising: an elongated tubular member (12) having proximal and distal sections, an outer surface, and at least one lumen (11) extending therethrough, and annular insulation (16, 22) having proximal and distal ends arranged concentrically (Fig. 1) around the outer surface of the elongated tubular member (12) is insulated from fluid or tissue external to the annular insulation (16, 22), wherein the insulation is tapered (at 18), extends along substantially the whole length or a shorter section of the catheter (col 16, lines 54-59) and comprises a fluid-filled member, filled with gas, water or saline (col 9, line 66 - col 10 line 2) and polymeric material (14, 20, col 10, lines 38-39). Regarding claim 30, the structure can be used for brain cooling.

Claims 20-24, 27 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Ginsburg (6,033,383). Ginsburg shows a catheter for intravascular corporeal cooling comprising: an elongated tubular member (20) having proximal (24) and distal (26) sections, an outer surface, and at least one lumen (28) extending therethrough, and annular insulation (18, 32, 34) having proximal and distal ends arranged concentrically (Fig. 2) around the outer surface of the elongated tubular member (20) is insulated from fluid or tissue external to the annular insulation (col 6, lines 6-13), wherein the insulation is tapered (Fig. 11) and comprises a fluid-filled member, and at least one lumen is in communication with a source of cooled blood and/or a liquid pharmaceutical source (col 4, lines 1-13), which can be used for brain cooling (col 4, line 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg in view of Donlon (6,056,723). Ginsburg shows all of the limitations of claim 29 except for the pressure sensor. Donlon shows a similar catheter for placement in a blood vessel

which includes a pressure sensor (38). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a pressure sensor in the device of Ginsburg to prevent injury by which can be caused by high pressure fluids in the bloodstream.

Response to Arguments

In response to applicant's argument that the primary purpose of the claimed invention is to diminish heat transfer, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The prior art allows for regulation of the temperature of the fluid within the catheter, and the structure of the device is disclosed as being usable for either heating or cooling.

Conclusion

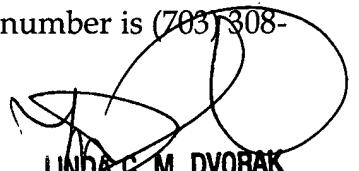
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jocelyn D Ram whose telephone number is (703) 308-6392. The examiner can normally be reached on Mon-Fri, 10-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

JR
February 11, 2003